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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,798	01/16/2004	Stanley J. Wiegand	REG 980A	6501
26693	7590	01/04/2006	EXAMINER	
REGENERON PHARMACEUTICALS, INC 777 OLD SAW MILL RIVER ROAD TARRYTOWN, NY 10591			LOCKARD, JON MCCLELLAND	
			ART UNIT	PAPER NUMBER

1647

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/758,798

Applicant(s)

WIEGAND ET AL.

Examiner

Jon M. Lockard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to a method for identifying an agent capable of inhibiting binding of a ligand of neuromedin U receptor 2 (NMUR2) protein, classified in class 436, subclass 501, for example.
  - II. Claims 2-5, drawn to a method for identifying an agent capable of modulating a neuromedin U receptor 2 (NMUR2) protein *in vivo*, classification dependent upon compound structure.
  - III. Claims 6-13, drawn to a method for inhibiting pain or nociception comprising administering an agent capable of modulating NMUR2 activity, classification dependent upon compound structure.
  - IV. Claims 14-16, drawn to transgenic animals, classified in class 800, subclass 13, for example.
2. The inventions are distinct, each from the other because of the following reasons:
3. Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentable distinct inventions for the following reasons: Inventions I-III are directed to methods that are distinct both physically and functionally, have different method steps, starting compounds, and goals, and are not required one for the other. Invention I requires search and consideration of identifying an agent capable

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of inhibiting binding of a ligand of neuromedin U receptor 2 (NMUR2) protein, which is not required by any of the other Inventions. Invention II requires search and consideration of identifying an agent capable of modulating a neuromedin U receptor 2 (NMUR2) protein *in vivo*, which is not required by any of the other inventions. Invention III requires search and consideration of inhibiting pain or nociception comprising administering an agent capable of modulating NMUR2 activity, which is not required by any of the other inventions. Therefore, each method is divergent in materials and steps. For these reasons, Inventions I-III are patentably distinct. Furthermore, the distinct steps and products require separate and distinct, non-coextensive searches. The inventions of Groups I-III have a separate status in the art as shown by their separate search requirements. As such, it would be burdensome to search the inventions of Groups I-III together.

4. Inventions IV and each of Invention I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different Inventions of IV and each of I, II, and III are unrelated product and methods, wherein each is not required, one for another. For example, the claimed Inventions I, II, and III do not require the use of the transgenic animals of Invention IV.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and/or separate search requirement, restriction for examination purposes as indicated is

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proper.

*Election of Species*

6. In addition to the above Restriction Requirements, a further election of species is required as follows:

**If Applicants elect Invention III**

7. This application contains claims directed to the following patentably distinct species of the claimed invention: one of the following species of pain disorder: chronic fatigue syndrome, fibromyalgia, or chronic pain resulting from an injury to the body. Each pain disorder is considered to constitute a patentably distinct species because they have different etiologies, symptoms, and physiological results, and would require separate search and consideration. Search of more than one sequence would constitute a burden on the Office.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6-12 are generic.

9. Applicant is advised that a reply to this requirement must include an identification of the single species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML

December 28, 2005

*Bridget C. Bunner*

**BRIDGET BUNNER  
PATENT EXAMINER**